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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176
29156 7590 09/21/2007 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/044,113

Applicant(s)

REAM ET AL.

Examiner

Hasan S. Ahmed

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 21-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' remarks, filed on 27 June 2007.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 8-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,541,048 to Zyck et al. ("Zyck").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Zyck teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (see col. 10, line 3);

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- the coating comprising a medicament of instant claims 8 and 16 (see col. 2, lines 18-23);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 10, line 29);
- the antacids of instant claims 9 and 17 (see col. 2, lines 18-23);
- the taste masking agent of instant claims 10, 12, and 19 (see col. 8, line 55);
- the xylitol of instant claim 11 (see col. 8, line 55);
- the aspartame of instant claims 13 and 20 (see col. 7, line 49); and
- the gummi confectionaries of instant claims 14 and 18 (see col. 1, line 65 – col. 2, lines 25-27).

Zyck does not disclose a shellac layer.

*

2. Claims 8-14 and 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,627,234 to Johnson, et al. ("Johnson").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnson teaches a product comprising a medicament comprising:

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- the consumable tableted center of instant claims 8 and 16 (see col. 10, line 57);
- the coating comprising a medicament of instant claims 8 and 16 (see col. 2, lines 59-66);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 15, line 41);
- the analgesics of instant claims 9 and 17 (see col. 5, line 65);
- the taste masking agent of instant claims 10, 12, and 19 (see col. 12, line 38);
- the xylitol of instant claim 11 (see col. 12, line 38);
- the aspartame of instant claims 13 and 20 (see col. 9, line 27); and
- the gummi confectionaries of instant claims 14 and 18 (see col. 2, lines 59-66).

*

3. Claims 8-14 and 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,163,705 to Johnson, et al. ("Johnson").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnson teaches a product comprising a medicament comprising:

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- the consumable tableted center of instant claims 8 and 16 (see col. 13, line 51);
- the coating comprising a medicament of instant claims 8 and 16 (see col. 3, lines 16-19);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 12, line 1);
- the muscle relaxants of instant claims 9 and 17 (see col. 5, line 9);
- the taste masking agent of instant claims 10, 12, and 19 (see col. 13, line 66);
- the xylitol of instant claim 11 (see col. 13, line 66);
- the aspartame of instant claims 13 and 20 (see col. 13, line 17); and
- the gummi confectionaries of instant claims 14 and 18 (see col. 3, lines 16-19).

*

4. Claims 8-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,645,535 to Zyck et al. ("Zyck").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Zyck teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (see col. 10, line 37);
- the coating comprising a medicament of instant claims 8 and 16 (see col. 2, lines 33-44);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 9, line 9);
- the antacids of instant claims 9 and 17 (see col. 2, lines 33-44);
- the taste masking agent of instant claims 10, 12, and 19 (see col. 9, line 17);
- the xylitol of instant claim 11 (see col. 9, line 17);
- the aspartame of instant claims 13 and 20 (see col. 8, line 13); and
- the gummi confectionaries of instant claims 14 and 18 (see col. 2, lines 33-44).

Zyck does not disclose a shellac layer.

* * * * *

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,056,541 to Stahl ("Stahl").

Stahl teaches a product comprising a medicament comprising:

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- the consumable tableted center of instant claims 8 and 16 (see col. 1, line 38);
- the coating comprising a medicament of instant claims 8 and 16 (see col. 2, lines 37-49);
- the vitamins of instant claims 9 and 17 (see col. 5, line 17);
- the taste masking agent of instant claims 10, 12, and 19 (see col. 7, line 21);
- the xylitol of instant claim 11 (see col. 7, line 21);
- the aspartame of instant claims 13 and 20 (see col. 5, line 10); and
- the gummi confectionaries of instant claims 14 and 18 (see col. 1, line 65 – col. 2, line 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to omit the shellac layer of instant claim 15, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

Stahl explains that adding a medicament to the coating is beneficial because, "...active substance(s) is/are exposed to the consumer within a short period of chewing." See col. 2, lines 52-53.

While Stahl does not explicitly teach the percentages of instant claims 8, 12, 13, 16, and 20, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative

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experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a product comprising a consumable tableted center and a coating comprising a medicament, as taught by Stahl. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a product because it quick exposure of medicament to the consumer, as explained by Stahl.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional

Claims 8-20 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 09/990,628; 10/206492; 11/269,980; 11/273,941; and 11/273,942.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the each of the above-cited copending applications claim similar subject matter. For example, Application No. 10/206,492 recites a product including a medicament comprising a tableted center and a coating including a medicament (see claim 8). Thus, the compositions recited in the claims of the copending applications listed above are directly within the scope of the compositions of the instant claims.

This is a genus-species situation, wherein the numerous species of the copending application claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

Additional properties claimed are inherent by the use of the particular formulation – a product comprising a consumable center and a coating comprising a medicament – in combination with excipients known in the art.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search

of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as claimed. The Examiner requests a complete list of both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

Non-Provisional

Claims 8-20 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Nos. 6,355,265; 6,541,048; 6,426,090; 6,322,806; 6,290,985; 6,627,234; 6,465,003; 7,163,705; 6,773,716; 6,645,535; 6,558,692; and 6,355,265. Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the claims of the instant application and each of the above-cited U.S. Patents.

For example, U.S. Patent No. 6,322,806 recites a product including a medicament comprising a tableted gum center and a coating including a medicament (see claim 1). Thus, the compositions recited in the claims of the U.S. Patents listed above are directly within the scope of the compositions of the instant claims.

This is a genus-species situation, wherein the numerous species of the U.S. Patent claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

Additional properties claimed are inherent by the use of the particular formulation – a product comprising a consumable center and a coating comprising a medicament – in combination with excipients known in the art.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of U.S. Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the U.S. Patents above that appear to have similar subject matter as claimed. The Examiner requests a complete list of both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

* * * * *

Response to Arguments

Applicant's arguments filed on 27 June 2007 have been fully considered but they are not persuasive.

Applicants argue that the instant application is distinguished from the cited prior art because the phrase "consumable center" does not encompass the concept of a chewing gum. See remarks, filed 27 June 2007.

Examiner respectfully submits that the instant specification is replete with descriptions and examples that read on the concept of the chewing gum; examples include, *inter alia*:

- instant claims 14 and 18 recite a consumable center comprising gummy confectionaries;
- the consumable center may comprise a gummi candy (see page 5, line 16);
- drug delivery is provided by, "...chewing the product to cause the medicament to be released from the product into the buccal cavity of the chewer; and continuing to chew the product thereby creating a fluid pressure causing the medicament to enter the systemic system of the chewer through the oral mucosa contained in the buccal cavity." see page 6, lines 22-26;
- an advantage recited by the instant application is, "...to provide a chewable product that contains an agent that heretofore could not be provided in a chewable form that was palatable." see page 8, lines 11-13.

Perhaps the most telling indicators that the phrase "consumable center" includes chewing gum are example 1 (see instant specification, pages 22-25) and example 2 (see instant specification, pages 22-25) which are explicit examples of a consumable center comprised of chewing gum.

As such, examiner respectfully submits that the prior art reads on the instant claims in view of the instant specification.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


HUMERA N. SHEIKH
PRIMARY EXAMINER